The Examiner rejects claims 1, 2, 4, 5, 8, 10, 12, 14-24, under 35 U.S.C. §102(6), as being anticipated by Hsu, et al.

Applicant(s) respectfully submit that the deletion of claims 1, 2, 4, 5, 8, 10, 12, 14-24 has rendered the Examiner's rejection moot.

The Examiner requests claims 1, 2, 8, 10-14 and 20, under 35 U.S.C. §102(b), as being anticipated by Senbo.

Applicant(s) respectfully submit that the deletion of claims 1, 2, 8, 10-14 and 20 has rendered the Examiner's rejection moot.

The Examiner rejects claims 1, 2, 4-8, 10-14 and 16-21, under 35 U.S.C. § 102(e), as being anticipated by Miller. The Examiner states that mixing ingredients and forming a solid matrix, then surgically implanting, to obtain slow release (column 7, lines 5-21) of an endoparainticidal agent effective in dogs, -- sheep – (column 4, line 5-20), avermectins and milbemycins and derivatives, thus, the instant non-critical form, doramectin (column 5, line 49-60). Tablets include the instant excipients (Example 1) BHA, BHT may be added (column 8, top) disintegrants include starches and PVP (column 9, lines 29-48). Sterilization is shown (Example 9). The device is molded, thus of any desired shape-inclusive of a non-critical rod.

Applicant(s) respectfully submit that claim 7 of the present invention parasiticidal compound having an aqueous solubility below 100 mg/ml and tableting excipients which include magnesium stearate. Applicant(s) further submit that the Miller reference does not disclose nor teach the specific embodiements of the present invention and request that the Examiner's rejection be withdrawn.

The Examiner rejects claims 1, 2, 4-24, under 35 U.S.C. § 103(a), as being unpatentable over Shih et al. EPO 473223 in view of Hsu, Miller or Dinnetta.

Hsu and Miller taken alone or in combination do not mention or suggest the solid implants and methods of treatment claimed in the present invention for the same reasons provided above. Hsu fails to disclose specific excipients or provide an enabling disclosure with respect to solid implants and Senbo fails to mention implants at all.

The primary reference, Shih et al., describes a bioerodable implant comprising either a poly(orthoester) or a polyacetal. The implants described by Shih et al. are highly specialized and of unique design and the beneficial drug must be subject to condensation with diketene acetals or divinyl ethers and the drug is covalently linked with the polymer

chain backbone. This type of implant is entirely different from that of the present invention, which simply comprises a solid implant comprising at least one parasiticidal compound having an aqueous solubility below 100 μg/ml and one or more tabletting excipients including a bulking agent.

Dinnetta teaches the administration of avermectin compounds, however, nowhere does Dinnetta mention or suggest a solid implant comprising at least one parasiticidal compound having an aqueous solubility below 100 μg/ml and one or more tabletting excipients including a bulking agent.

Even if Shih et al. were combined with the descriptions provided in Hsu, the present invention would not result. The Examiner comments that it would have been obvious to use Shih and Hsu implants, modified as desired to optimize production as shown by Senbo and Roorda. Yet Shih and Hsu each describe devices that are highly specialized and entirely different in design from the present invention. The present invention is not an optimization of either Shih or Hsu, but rather a solid implant which is much simplified over the cited references and is particularly suited to convenient administration for prolonged protection. The implant of the present invention is produced using simple methods as described in the specification and does not require prior chemical reaction of the active drug or covalent attachment of the drug to a polymeric backbone. While the use of various bulking agents or antioxidants may have been known for use in various parasiticidal formulations, none of the cited references, taken alone or in combination describe the particular combination of elements presented in the claims of the present invention. It would not have been obvious to combine those particular elements from the cited references, such as Miller and Dinnetta without any suggestion to do so, and it would not have been obvious that the combination as claimed in present invention would be useful in treating parasitic infections in view of the simplicity of manufacture and design. The rejection under 35 U.S.C. § 103(a) should therefore be withdrawn.

Enclosed herewith, is a marked up version of the changes made to the specification entitiled "VERSION WITH MARKINGS TO SHOW CHANGES MADE".

In view of the present amendment and remarks, Applicant believes the present application contains patentable subject matter and respectfully requests a timely Notice of Allowance be issued for claims 7 and 9.

Respectfully submitted,

Date: 11/12/02

B. Timothy Creagan
Attorney for Applicant(s)
Reg. No. 39,156

Pfizer Inc.
Patent Department, MS 8260-1611
Eastern Point Road
Groton, Connecticut 06340
(860) 715-4546

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims

Please delete claims 1, 2, 4, 5, 8, 10-24.

In the Abstract

After the claims please insert the following Abstract on a separate page.

--PARASITICIDAL FORMULATIONS

Abstract

This invention relates to a solid implant containing a parasiticidal compound having low aqueous solubility, which is particularly useful for administration to livestock such as cattle, pigs and sheep--